Keynote Address of Representative Henry A. Waxman
The Food and Drug Law Institute (FDLI) Conference
"Celebrating the 30th Anniversary of the
Hatch-Waxman Amendments:
The Past, Present and Future of Generic Drugs"
September 18, 2014

I am pleased to join you today. Needless to say, the focus of this conference, the Hatch Waxman Act, is near and dear to my heart.

I want to thank the Food and Drug Law Institute for inviting me to speak to you. For years, the institute has been a leader in the area of FDA law and has done a fantastic job of bringing together the best and brightest minds to discuss issues of critical importance to the public health.

History

Thirty years ago, the U.S. generic drug industry was in severe decline. The 1962 amendments to the Federal Food, Drug, and Cosmetic Act added a requirement that manufacturers demonstrate that their drugs were effective in addition to being safe. This was a reaction to the thalidomide tragedy in Europe, and was a critically important advance in drug oversight in the United States.

But it was a real problem for generic drug manufacturers. FDA interpreted this new effectiveness requirement to mean that generic drug manufacturers had to conduct full clinical trials on drugs that had already been shown by the brand manufacturer to be safe and effective. These trials were not only unnecessary and duplicative, they were effectively a death knell for generic manufacturers. We knew we had to do something to fix this situation.

At the same time, many in Congress were focused on helping the brand industry, which was clamoring to receive patent term restoration to compensate them for the time they expended in meeting the 1962 requirements.

In 1984, I worked with Senator Hatch to pass legislation that addressed both of these concerns. It was balanced legislation, which supported both brand innovation and generic competition. And the legislation has proved to be enormously important and successful.

Consumers have benefited. Over eighty per cent of all U.S. prescriptions are now filled by generics. The U.S. healthcare system and consumers saved over $200 billion dollars last year due to generic drugs, and well over a trillion dollars over the last decade.

But at the same time, the brand drug industry continues to be one of the most profitable sectors in the United States.

Abuses and Controversies

In the years since passage of Hatch Waxman, Congress has enacted other laws to promote generics and help the brand industry thrive. In 1992, Congress enacted the Prescription Drug User Fee Act to accelerate FDA review of brand name drugs. Just last Congress, we finally acted to pass the first Generic Drug User Fee Amendments or "GDUFA" in 2012.

A major backlog of generic applications had amassed at FDA, which resulted in long and unnecessary delays in the emergence of generic drugs and the savings they bring. With GDUFA, FDA now has the resources it needs to eliminate the backlog of old applications and speed up approvals of new applications.

Overall, I think we have gotten the balance right. Both the brand and generic industries are thriving, and that is important for our health care system.

But as I prepare to leave Congress after 40 years, there are threats to this balance on the horizon. And I would like to talk about some of them.

One current roadblock for generic competition is the use by brand manufacturers of Risk Evaluation and Mitigation Strategies, or REMS, to prevent

or delay generic competition. In 2007, we gave FDA the authority to require REMS on certain drugs in order to give additional assurance that the drug could be used safely once it was on the market.

One type of REMS allows FDA to require the companies to restrict the distribution of the drug to only certain types of providers or facilities. However, these REMS have increasingly been used as an excuse for refusing to sell the brand drug to generic drug companies. Without obtaining samples of the brand drug, the generic manufacturer cannot conduct the bioequivalence studies necessary for approval. Sometimes a brand manufacturer will find ways, through patents or other means, to make it difficult for a generic manufacturer to implement a REMS procedure that FDA mandates as a condition of approval.

The result is a major delay in the ability of generic companies to seek FDA review of their applications. This practice distorts the congressional intent underlying the REMS provisions. In giving FDA new tools to protect the American people from unsafe drugs, Congress by no means intended to supply brands with new tools to thwart generic competition.

We tried to address this issue last Congress, when I supported a legislative fix being added to the 2012 user fee legislation. CBO found this fix would produce large savings for the federal government because delay in generic competition deprives the healthcare system of cost savings. Unfortunately, that fix was not ultimately adopted. I hope Congress will take up legislation soon to address this practice.

Another way that companies have exploited loopholes in Hatch Waxman is through the use of so-called "reverse-payment" settlement agreements. These are agreements in which a patent holder pays a potential competitor not to challenge its patent. Last year, the Supreme Court recognized that these settlements can be anticompetitive. The Court ruled that the Federal Trade Commission should look at factors, such as the size of the payment and the anticompetitive effects, to help decide whether a settlement is anticompetitive. The Supreme Court's opinion made it clear that while settlement agreements with reverse payments are not necessarily illegal, they should be viewed with suspicion.

I want to be clear that I am not against patent settlements *per se*. I recognize that it can be in everyone's interest to avoid costly and time-consuming patent litigation. However, when a generic firm commits to stay off the market in exchange for payment, there is always potential for abuse. The President, in his 2015 budget, recommends passage of legislation that would give the Federal Trade Commission greater ability to block anticompetitive patent settlements that involve payments. I think this proposal is a sound one.

In addition to trying to fix existing problems with Hatch Waxman, we have to be on the alert for legislation that might create new problems. One bill that could have unintended impacts is the MODDERN Cures Act. It has forty co-sponsors, almost half of whom are Democrats.

The purpose of the legislation is to provide incentives for development of promising drugs that have been abandoned because of lack of patent protection. Proponents of the bill refer to such drugs as "dormant therapies." There may well be a need to figure out how to increase the incentives to develop such drugs. I am always interested in finding better ways to create incentives for the development of needed new medicines. I think my work to get the Orphan Drug Act passed demonstrates that beyond dispute.

My concern, however, is that the MODDERN Cures Act lacks the balance that Congress has worked hard to maintain for the past 30 years since passage of Hatch Waxman. As currently written, the bill would give 15 years of market exclusivity, post approval, to almost any drug that was considered to fulfil an unmet medical need. That is a very long time.

In comparison, the Orphan Drug Act gives only seven years market exclusivity to orphan drugs, and those are for diseases that affect fewer than 200,000 Americans. The Orphan Drug Act has been, by all accounts, a resounding success in bringing new drugs to market.

This bill has been discussed in the context of the "21st Century Cures Initiative" spearheaded by Reps. Upton and DeGette in the Energy and Commerce Committee. This has led to some interesting and productive discussions. But I

hope that as the legislative phase of that initiative starts next year, Congress will be cautious about altering the careful balance between innovation and affordability that Hatch Waxman represents.

The 2011 Supreme Court decision, *Pliva v. Mensing,* also raises challenging issues for the generic industry. In that decision, the Supreme Court ruled that because generic drug manufacturers need FDA approval before putting a new safety warning on their products, they could not be sued for failing to warn consumers about risks not on the FDA-approved warning label. I had submitted an amicus brief supporting the Administration's alternative view, which was that generic drug manufacturers should be held liable if they did not seek FDA approval for a new warning label when warranted. The Supreme Court did not agree.

The Supreme Court decision led FDA to review its regulations regarding how manufacturers go about making changes to warning labels. Last year, FDA published a proposed rule that would treat brand and generic manufacturers the same with regard to such label changes. It would allow generics, like brands, to update safety labeling prior to receiving FDA approval. It establishes a mechanism to provide information about the change to other manufacturers and to practitioners and patients. And it establishes procedures to minimize the time during which there would be temporary labeling differences among products.

FDA believes this process will help get new drug safety information out to patients and doctors more quickly. This process will also restore state tort liability, which serves as an important incentive for generic drug manufacturers to comply with post-approval monitoring and reporting requirements. FDA has long believed – and I agree – that the state tort liability system is a critical complement to FDA's compliance and enforcement activities.

One trade-off is that there may be more temporary differences in labeling among products than occurs now, when only the brand can change its label on its own. However, currently there are also temporary labeling differences between brands and generics, so the FDA rule would not be drastically changing the situation.

I recognize that more liability can translate to higher cost of liability protection. The generic drug industry operates on thin margins, so any added costs are noticeable. But it is important to recognize that the generic drug industry grew and prospered for decades before the *Mensing* decision. I am confident the industry can under the new FDA rules too.

Sovaldi

There are also challenges facing the brand industry. One involves recent pricing trends. Perhaps the most striking example of this trend is Gilead's Hepatitis C drug, Sovaldi.

From what I understand, Sovaldi is a real advance in treating Hepatitis C. It has a high cure rate, and the treatment takes only 12 weeks, half the time of other treatments. And it does not have the awful side effects that make the other treatments intolerable for some patients. It thus can make a real difference in the lives of the more than three million Americans with a chronic Hepatitis C infection.

However, at a cost of $1,000 a pill, many patients may not be able to get the drug. A 12 week course will run $84,000. When given in combination with the other drugs required for treatment, total costs can reach $150,000 or more. Hepatitis C infection is concentrated in low-income minority patients, so the cost will be a particular problem for state Medicaid programs and their patients.

I know that companies need to make a profit. In fact, one of the attributes of the pharmaceutical industry is that it's an area where a company can do well by doing good. But this is another area where striking the right balance is essential. If a new drug is so expensive that patients cannot afford it, no one benefits.

I understand that Gilead recently reached an agreement to authorize the sale of a generic version of Sovaldi at much lower prices in developing countries. That is an encouraging step because developing countries can benefit from access to an

affordable version of this drug. But it does not resolve the cost concerns that Medicaid and other programs are facing with this drug.

Biosimilars

Sovaldi is a drug, not a biologic, but the majority of our most expensive new medicines are biologics. That is why it was so important that Congress establish a pathway for the approval of less expensive biosimilar versions of biologics as part of the Affordable Care Act.

When we were working on the legislation, I was pushing for five years of exclusivity, which would be the same as that for conventional drugs. Unfortunately, I did not prevail. The final law gave brand biologics 12 years exclusivity. I think 12 years is too much.

The President has proposed in this year's budget that the period be reduced to seven years, as he has in past budgets. I hope he will be successful in reducing the time period.

But whatever the length of exclusivity, it is important that this law be implemented successfully. My sense is that FDA has been making great progress. It has been holding public meetings, developing guidances, and putting in place the policies necessary for review and approval of biosimilar applications. I hope that the agency will continue its good work in this area.

I am not so optimistic about another set of activities aimed at interchangeable biosimilars. BIO and a few companies, both brand and generic, are trying to get states to enact laws that will require pharmacies to notify a patient's physician before dispensing an interchangeable biosimilar. These policies are being touted by supporters as necessary to protect patients and keep physicians informed of the medicines their patients are receiving.

I fear the more likely effect will be to stigmatize interchangeable biosimilars and make patients and physicians think twice before using them.

There is little dispute that biologics are part of the future of medicine. But these life-saving therapies also need to be affordable if they are going to fulfill their potential. That is why we need to make sure that policies are in place that will permit both the brand and generic biologic industry to thrive.

Conclusion

I want to close by thanking you for the opportunity to speak to you today, in this year of the 30th anniversary of Hatch Waxman. I am proud of the success the law has had in bringing competition to the marketplace. As many of you know, I will not be running for office after this term. I have not decided what I will be doing after I leave Congress, but you can be assured I will continue to work to promote competition and innovation in our prescription drug industry.

Thank you. I would be happy to take any questions you may have.